

REMARKS/ARGUMENTS

Claims 1 and 13-16 stand rejected by the Examiner as allegedly anticipated by Simard et al., and in a separate rejection, claims 1-2 and 13-16 stand rejected as allegedly anticipated by Couillard et al. In finding Applicant's prior arguments unpersuasive, the Examiner indicates on page 3 of the Office Action that "there is no explicit limitation in the claims reciting a 'pharmaceutical dosage form.'" It is urged that perhaps both of these anticipation rejections may be based on a simple misapprehension of the relevant language in the rejected claims. Specifically, the Examiner's attention is drawn to the final clause of claim 1 (from which all other rejected claims are dependent directly or indirectly), which reads "wherein said composition is a pharmaceutical dosage form suitable for administering to a patient." (See the most recent amendment to the claims filed June 22, 2007). In both cited references, SERMs and estrogens are only intermixed (1) in the body of laboratory animals or (2) in culture media or other environments which cannot in any way be considered "a pharmaceutical dosage form suitable for administering to a patient." The Examiner notes that ethanol is used in Simard, and Water in Couillard. However, the fact that substances that could be useful in pharmaceutical preparations are also present, cannot change blood, animal tissue or culture media into "pharmaceutical dosage forms."

Claims 17-19, 22-23 and 35-41 stand rejected under 35 U.S.C. §103 as allegedly obvious over Simard or Couillard. In Applicant's prior response, it was pointed out that these references teach against the use of estrogen as required by the present claims. At page 8 of the Office Action, the Examiner states that this is not relevant to an anticipation rejection. However, Applicant raises the issue of the art teaching away from the invention only in the context of the present obviousness rejection.

All claims require "estrogen" while both the Simard reference and the Couillard reference teach against estrogen. Couillard notes (at abstract lines 6-7) that "Estrone caused a 10-fold increase in ZR-75-1 tumor area . . ." ZR-75-1 is defined as human mammary tumor. Likewise, Simard states that "estrogens play a predominant role in the development and growth of human breast cancer . . ." (Abstract, lines 1-2). In the context of the present obviousness rejection, this "teaching away" is both relevant (See MPEP 2144.08) and conclusive that the invention is not

obvious. The claims rejected for obviousness over Simard and Cuillard are distinguishable by their requirement of “estrogen,” which Simard and Cuillard teach should be avoided. While the Examiner is correct that such “teaching away” is not relevant to the above anticipation rejection, “teaching away” is of critical importance on the issue of obviousness. Thus, the rejection under 35 U.S.C. §103 over the combination of Simard and Couillard should be withdrawn.

Claims 1-2, 13-19, 22-23 and 35-41 stand rejected as allegedly obvious over the combination of Luo et al., Barrett-Connor et al. and Do Nascimento in view of Labrie et al. The Examiner concedes that these references do not utilize estrogen and SERMs in combination, but contends the cited references disclose the use of each separately for the same purpose. Applicant traverses the contention that the cited art discloses these agents separately for the same purpose.

The Examiner relies upon *In re Kerkhoven* 626 F2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). However, *Kerkhoven* specifically requires that combining agents used in the prior art only creates a *prima facie* case of obviousness when the prior art’s individual use of such agents is for the same purpose. In responding to Applicant’s prior arguments that *Kerkhoven* does not apply, the Examiner appears to have misunderstood the reason that Applicant pointed out Barrett-Conner’s failure to address cholesterol levels. Applicant noted this failing in Barrett-Conner to show that it is improper under *Kerkhoven* to combine the teachings of Barrett-Conner with Nascimento. The Examiner alleges that Nascimento discloses the use of estradiol for hypercholesterolemia. In order to rely upon the *Kerkhoven* case to combine Nascimento’s teachings with Barrett-Conner, however, it would be necessary to show that Barrett-Conner also uses its agents for the same purpose -- treatment of hypercholesterolemia. Different lipids may respond differently to different pharmaceutical agents. It is not appropriate under *Kerkhoven* to combine the teachings of Nascimento (hypercholesterolemia) with the teachings of Barrett-Conner unless Barrett-Conner utilizes its pharmaceutical agents for hypercholesterolemia. Accordingly, it is urged that it is not proper to combine the teachings of Nascimento and Barrett-Conner and that a *prima facie* case of obviousness has not been made.

Likewise, the Labrie reference is not properly combinable with Nascimento because the cited Labrie reference is also not alleged to disclose using its pharmaceutical agents for hypercholesterolemia.

Finally, as to the fourth reference, Luo, Applicant and the Examiner have reached an impasse on the issue of whether Luo discloses the use of estrogens. Applicant believes that it does not. As best Applicant can understand the Examiner's argument, the Examiner appears to be arguing that Luo's use of DHEA constitutes a use of estrogen. DHEA is not an estrogen. Applicant does not believe that one of skill in the art would define the term "estrogen" as including DHEA. Applicant does not define the term estrogen in that manner -- instead, listing DHEA as an "additional agent" in several claims (claim 23 for example). Moreover, in claim 1, subparagraph(b), the estrogens within scope of claim are specifically defined in a manner which does not include DHEA. Accordingly, it is urged that Luo is not relevant to the use of estrogens as presently claimed. Moreover, should the Examiner persist in contending that DHEA is understood in the art to be an estrogen, it is respectfully requested that a prior art reference be cited in support of that proposition.

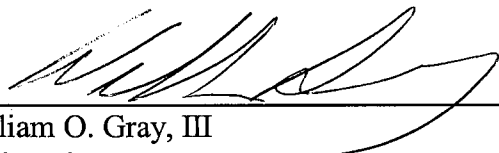
For all the foregoing reasons, it is urged that the obviousness rejection of Luo, Barrett-Conner, Nascimento and Labrie be withdrawn.

It is urged the application is now in condition for allowance. Issuance of a Notice of Allowance is solicited.

Respectfully submitted,

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